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No. 07-1327

In the Supreme Court of the United States

ALBERTSON'S, INC., ET AL., PETITIONERS

v.

JENNIFER KANTER, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, preempts respondents' suit to enforce state food-labeling requirements that are identical to requirements imposed under the FDCA.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, prohibits the misbranding of food in interstate commerce. 21 U.S.C. 331(a)-(c) and (k). A food containing artificial coloring is misbranded "unless it bears labeling stating that fact." 21 U.S.C. 343(k). The Food and Drug Administration (FDA), which has authority to regulate the labeling of food products, has promulgated regulations providing that farmed salmon may be fed certain color additives "to enhance the * * * color of th[eir] flesh," 21 C.F.R. 73.35(c)(1), 73.75(c)(3)(ii), but "[t]he presence of the color additive * * * shall be declared" in the labeling,

21 C.F.R. 73.35(d)(3), 73.75(d)(4). The declaration may be accomplished by identifying the specific color additive or, alternatively, by using "an * * * informative term" such as "'Color Added' * * * that makes clear that a color additive has been used in the food." 21 C.F.R. 101.22(k)(2). See 21 U.S.C. 371(a), 393(b)(2)(A) and (d)(2) (Secretary of Health and Human Services, through FDA, may promulgate regulations to implement, and is otherwise responsible for executing, the FDCA, including its food-labeling requirements).

In 1990, Congress amended the FDCA to include additional requirements relating to food labeling. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. The NLEA contains an express preemption provision that generally prohibits States from establishing or continuing in effect "any requirement for the labeling of food" with artificial coloring "that is not identical to the requirement[s]" of 21 U.S.C. 343(k). 21 U.S.C. 343-1(a)(3). The NLEA preemption provision contains specified exceptions, and it authorizes FDA to grant additional exemptions under certain circumstances. 21 U.S.C. 343-1. The NLEA states that its provisions "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [the NLEA]." § 6(c)(1), 104 Stat. 2364.

The FDCA provides that, in general, "proceedings for the enforcement, or to restrain violations, of the [FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). Under an amendment added by the NLEA, a State may also bring proceedings, "in its own name and within its jurisdiction," to enforce certain food-labeling provisions of the FDCA if the State complies with specified procedural requirements. 21

U.S.C. 337(b). In particular, before commencing proceedings, a State must notify FDA and provide adequate time for FDA to bring its own enforcement action. 21 U.S.C. 337(b)(2)(A)-(B). A State may not bring its own action to enforce the FDCA if FDA "is diligently prosecuting a proceeding in court" pertaining to the food in question, "has settled such proceeding, or has settled [an] informal or formal enforcement action pertaining to such food." 21 U.S.C. 337(b)(2)(C).

2. As permitted by Section 343-1, California regulates the labeling of food under the Sherman Food, Drug, and Cosmetic Law (Sherman Law), Cal. Health & Safety Code §§ 109875 *et seq.* (West 2006). Like the FDCA, the Sherman Law provides that a food containing artificial coloring is misbranded "unless its labeling states that fact." Compare *id.* § 110740 with 21 U.S.C. 343(k). The Sherman Law's specific labeling requirements directly incorporate regulations promulgated under the FDCA. See Cal. Health & Safety Code §§ 110085, 110090, 110100(a) (West 2006) (providing that current and future federal food-additive, color-additive, and food-labeling regulations shall be the "regulations of [California]"). California's food-labeling requirements are, therefore, substantively identical to the requirements of the FDCA.

3. Respondents, who are consumers of farmed salmon in California, filed a class action against petitioners in state court. Compl. paras. 1-4. Their complaint alleges causes of action for common-law negligent misrepresentation, as well as for violation of California consumer protection laws prohibiting unfair competition, false advertising, and unfair and deceptive trade practices. Compl. paras. 46-64; see Cal. Bus. & Prof. Code §§ 17200 *et seq.* (West 2008) (unfair competition); *id.*

§ 17500 (false advertising); Cal. Civ. Code §§ 1750 *et seq.* (West 1998) (unfair and deceptive trade practices). All four causes of action are based on the claim that petitioners "fail[ed] to label * * * farm-raised salmon as artificially colored * * * in violation of the [FDCA] and equivalent provisions of California law," including the Sherman Law. Compl. para. 28.

In response to a demurrer filed by petitioners, the California state trial court held that 21 U.S.C. 337 preempts respondents' suit. Pet. App. 51-65. Respondents elected not to amend their complaint, and the trial court dismissed the action. *Id.* at 40-41.

The California Court of Appeal affirmed the dismissal. Pet. App. 36-50. The court held that "section 337(a) impliedly preempts all of [respondents'] causes of action." *Id.* at 38. The court stated that, "[i]n section 337(a), Congress clearly expressed its intention to preclude private enforcement of the FDCA." *Id.* at 46. The preclusion of a private right of action under federal law, the court reasoned, reflected an effort to "afford[] the federal government a degree of oversight of the enforcement of the act." *Id.* at 46-47. In the court's view, allowing "a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and * * * conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme." *Id.* at 47. Accordingly, the court concluded that Section 337(a) impliedly preempts "any private state law cause of action" based on "conduct [that] would [violate] the FDCA." *Id.* at 47-48. The court explained that, if the facts "plaintiffs will necessarily have to prove in order to recover under their state law claims * * * demonstrate violations of the FDCA, then preemption

will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs." *Id.* at 49-50.

4. The California Supreme Court reversed and remanded for further proceedings. Pet. App. 1-35. The court held that the FDCA does not preempt respondents' suit to enforce state-law food-labeling requirements identical to FDCA requirements. *Id.* at 3.

The court first determined that 21 U.S.C. 343-1 indicates that States may enact and provide for enforcement of food-labeling requirements that are identical to FDCA requirements. Pet. App. 8-9, 17-27. The court reasoned that, "[a]lthough section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do." *Id.* at 9. In the court's view, "[t]he words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law." *Id.* at 17 (quoting 21 U.S.C. 343-1(a)(3)).

The court next concluded that "nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide" for violations of parallel state requirements. Pet. App. 27. The court observed that, "[w]hile Congress clearly stated its intent to allow states to establish their own identical laws, it said absolutely nothing about proscribing the range of available remedies states might choose to provide for the violation of those laws." *Id.* at 18. The court noted that Representative Waxman, who introduced the NLEA in the House of Representatives, explained that the state requirements "may be enforced in State court," without suggesting that enforcement would be restricted to actions brought by States themselves. *Ibid.* (quoting

136 Cong. Rec. 20,419 (1990)). The court reasoned that the absence of any suggestion that Congress intended to preclude private enforcement strongly suggests that it did not so intend, because Congress was presumably aware that "virtually every state in the nation permits one or more nongovernmental parties to enforce" state laws prohibiting unfair and deceptive practices. *Id.* at 20 (quoting Bob Cohen, Annotation, *Right to Private Action Under State Consumer Protection Act—Preconditions to Action*, 117 A.L.R.5th 155 (2004)). That conclusion, the court observed, is also supported by Section 6(c)(1) of the NLEA, which indicates that the preemptive effect of the NLEA "sweep[s] no further than the plain language of the statute itself." *Ibid.*

The California Supreme Court found additional support for its conclusion in this Court's decisions in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and *Bates* v. *Dow Agroscience LLC*, 544 U.S. 431 (2005). Pet. App. 24-26. The court noted that, in those cases, this Court construed preemption provisions that closely resemble Section 343-1 and concluded that those provisions authorized States not only "to adopt identical requirements" but also "to provide for private remedies for violations of those requirements." *Id.* at 25; see *id.* at 26. Accordingly, the state supreme court concluded, "Congress's decision not to expressly supplant private claims based on * * * state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies." *Id.* at 20.

The court then considered and rejected petitioners' contention that, notwithstanding Section 343-1, respondents' suit is impliedly preempted by 21 U.S.C. 337. The court observed that Section 337, "by its very terms, only

implicates efforts to enforce *federal* law." Pet. App. 29. Respondents, the court explained, "do not seek to enforce the FDCA; rather their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law." *Id.* at 28. "That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1," the court reasoned, "does not substantively transform [respondents'] action into one seeking to enforce the FDCA." *Ibid.*

The court noted that FDA has stated that Section 337 "applies only to proceedings to enforce the [FDCA]" and that therefore "[n]othing in [Section 337] would preclude a State from taking action against a particular food under *its own state law.*" Pet. App. 29 (quoting 58 Fed. Reg. 2458 (1993)) (brackets and italics added by court). Likewise, the court reasoned, Section 337 does not "affect the ability of states to provide a private remedy for violations of their laws if they so choose." *Id.* at 30.

The court also noted petitioners' admission that, notwithstanding Section 337(b), "states may enforce their own laws in state court without notifying FDA at all, even [when] the laws impose requirements identical to those contained in the FDCA." Pet. App. 34. The court observed that petitioners had failed to explain why private enforcement of state laws "would be of any greater concern to Congress than [state] enforcement of state laws," when "in both instances[] state laws identical to the FDCA are enforced without first notifying the FDA." *Ibid.* Accordingly, the court concluded that the FDCA "does not impliedly preempt private actions based on violations of state laws explicitly authorized by section 343-1." *Id.* at 35.

DISCUSSION

The California Supreme Court's ruling that the FDCA does not preempt respondents' state-law suit is correct. The state supreme court's decision does not conflict with any decision of this Court or a federal court of appeals. Moreover, the state supreme court's decision is interlocutory, and further proceedings may clarify the nature of any preemption issue that might be presented. Accordingly, the Court should deny the petition for a writ of certiorari.

A. The Decision Below Is Correct

The California Supreme Court correctly held that the FDCA does not preempt respondents' action to enforce state food-labeling requirements that are identical to requirements imposed under the FDCA. Under 21 U.S.C. 343-1, States are generally permitted to enact and to provide for the enforcement of those state requirements. Although 21 U.S.C. 337 precludes private actions to enforce the FDCA itself, Section 337 does not prohibit private actions to enforce parallel state requirements. A particular state-law suit might, in certain circumstances, impliedly conflict with provisions of the FDCA, implementing regulations, or a particular determination or enforcement action by FDA, but respondents' suit poses no such conflict.

1. Because Section 343-1 expressly addresses preemption of state food-labeling requirements, analysis of the preemption question "must in the first instance focus on the plain wording of [that provision], which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 664 (1993). As the California Supreme Court correctly concluded, Section 343-1 indicates that Congress gener-

ally intended to permit States to adopt food-labeling requirements identical to FDCA requirements and to provide for the enforcement of those state requirements in state court. See Pet. App. 17-27.

The plain text of Section 343-1 prohibits States from adopting "any requirement for the labeling of food" with artificial coloring "that is *not* identical to the requirement[s]" of 21 U.S.C. 343(k), the FDCA provision addressing artificial coloring. 21 U.S.C. 343-1(a)(3) (emphasis added). As the California Supreme Court recognized, by preempting only requirements that are "not identical" to federal requirements, Section 343-1 strongly suggests that States *may* adopt requirements that *are* identical to federal requirements. Pet. App. 9, 17. That conclusion is strengthened by Section 6(c)(1) of the NLEA, which indicates that Congress did not intend the preemptive effect of any provision of the NLEA, including Section 343-1, to extend beyond its express language. See 21 U.S.C. 343-1 note.

As the California Supreme Court also correctly concluded, nothing in Section 343-1 suggests that Congress intended to limit the States' authority to prescribe the remedies for violations of the state requirements permitted by Section 343-1. Pet. App. 18-27. "States are independent sovereigns with plenary authority to make and enforce their own laws as long as they do not infringe on federal constitutional guarantees." *Danforth* v. *Minnesota*, 128 S. Ct. 1029, 1041 (2008). Although Congress, under the Supremacy Clause, may displace the remedies States have provided for violations of state law that does not conflict with federal law as a substantive matter, this Court has been hesitant to conclude that Congress intends such "a serious intrusion into state sovereignty." *Medtronic, Inc.* v. *Lohr*, 518 U.S.

470, 488 (1996) (plurality opinion). Moreover, when Congress enacted Section 343-1, it presumably was aware that the vast majority of States permitted private parties to enforce state laws prohibiting deceptive business practices. See Pet. App. 20; Jeff Sovern, *Private Actions Under the Deceptive Trade Practices Acts: Reconsidering the FTC Act As Rule Model*, 52 Ohio St. L.J. 437, 448 (1991); see also U.S. Amicus Br. 3, *Altria Group, Inc.* v. *Good*, No. 07-562 (argued Oct. 6, 2008).[1] Against that backdrop, the absence of any indication that Congress intended to preclude States from authorizing private actions to enforce state substantive requirements that are not themselves preempted strongly suggests that Congress did not foreclose such suits.

The conclusion that Section 343-1 does not prevent States from providing private actions to enforce state requirements that mirror FDCA requirements accords with this Court's interpretation of similar preemption provisions. In *Lohr*, the Court construed 21 U.S.C. 360k, a provision of the FDCA that prohibits States from establishing "any requirement * * * different from, or in addition to," FDCA labeling and design requirements for medical devices. The Court concluded that Section 360k does not preempt "State or local requirements that are equal to, or *substantially identical* to, requirements imposed by or under the [FDCA]." 518 U.S. at 496-497 (emphasis added) (quoting 21 C.F.R. 808.1(d)(2)). All nine Justices also agreed that Section 360k permits States "to provide a traditional damages

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[1] As explained in the United States' amicus brief in *Wyeth* v. *Levine*, No. 06-1249 (argued Nov. 3, 2008), such suits would be preempted where the substantive state law to be applied conflicted with the FDCA, implementing regulations, or an approval or other determination made by FDA.

remedy for violations of" those identical state requirements. *Id.* at 495; see *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The Court recently reiterated that understanding of Section 360k in *Riegel* v. *Medtronic, Inc.*, 128 S. Ct. 999 (2008), observing that Section 360k "does not prevent a State from providing a damages remedy" where "the state duties" being enforced "'parallel,' rather than add to, federal requirements." *Id.* at 1011 (quoting *Lohr*, 518 U.S. at 495).

In *Bates* v. *Dow Agriscience LLC*, 544 U.S. 431 (2005), this Court adopted a similar interpretation of 7 U.S.C. 136v(b), a statutory provision prohibiting States from adopting "any requirements * * * in addition to or different from those required" by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* The Court held that, under the plain language of that provision, "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Bates*, 544 U.S. at 447. The Court further held that, "although FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy." *Id.* at 448. Consistent with *Lohr* and *Bates*, the California Supreme Court correctly concluded that Section 343-1 indicates that Congress did not intend to preclude States from providing private remedies for violation of state requirements that parallel requirements under the FDCA.

2. Notwithstanding Section 343-1, petitioners contend that Section 337 impliedly preempts respondents' suit. Petitioners assert that Section 337 precludes all private actions requiring proof of facts "that would sup-

port an FDCA claim" (Pet. 16), including suits under state law to enforce the parallel state requirements authorized by Section 343-1. Apparently relying on the principle that state law is impliedly preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), petitioners contend that private actions to enforce parallel state requirements would interfere with the "exclusive government enforcement scheme" that they assert is embodied in Section 337. Pet. 13. The California Supreme Court correctly rejected petitioners' contentions. See Pet. App. 27-35.

a. Nothing in the text of Section 337 suggests that it precludes actions under state law. Section 337(a) provides that, in general, "proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). Section 337(b) authorizes a State to bring an action to enforce specified provisions of the FDCA provided that the State complies with procedural requirements designed to ensure coordination with the FDA. 21 U.S.C. 337(b).

As FDA recognized when it promulgated regulations to implement Section 337(b), Section 337 "applies only to proceedings to enforce the [FDCA]." 58 Fed. Reg. at 2458. Accordingly, FDA concluded that Section 337 "does not prohibit a State from enforcing an identical State law." *Ibid.* Similarly, Section 337 does not prohibit a State from authorizing private suits to enforce such a law. Pet. App. 30.

Actions to enforce state laws that impose requirements identical to those under the FDCA are not actions to enforce the FDCA itself. Petitioners contend that

such state actions always "necessitate establishing a violation of federal standards." Pet. Reply Br. 6; see *id.* at 4. As respondents' suit itself demonstrates, however, that contention is incorrect. Respondents' suit "can be resolved with reference to state law alone." Pet. App. 33. Their claims are predicated on violations of California's Sherman Law, which provides that food is misbranded "if it bears or contains any * * * artificial coloring * * * unless its labeling states that fact." Cal. Health & Safety Code § 110740 (West 2006). Although that requirement mirrors the FDCA's requirement in 21 U.S.C. 343(k), respondents can prove that petitioners violated the Sherman Law requirement without even referring to the FDCA.

Respondents can also prove that petitioners violated the Sherman Law by proving that they violated FDCA regulations, Cal. Health & Safety Code § 110100(a) (West 2006), and respondents' complaint contains such allegations, Compl. para. 28. But, as this Court has explained, even when state-law claims are predicated on violations of the FDCA, they remain state-law claims. In *Lohr*, this Court held that the FDCA did not preempt state-law claims that included allegations that the defendant had "violated FDA regulations." 518 U.S. at 495. In *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court rejected the plaintiffs' "attempt to characterize * * * the claims at issue in [*Lohr*] * * * as 'claims arising from violations of FDCA requirements.'" *Id.* at 352 (citation omitted). As the Court explained, that characterization was inaccurate because the claims in *Lohr* arose from a state-law duty, "not solely from the violation of FDCA requirements." *Ibid.*; see also *Merrell Dow Pharm. Inc.* v. *Thompson*, 478 U.S. 804, 808, 809, 813 (1986). The same

is true of respondents' claims here.[2] "[T]he party who brings a suit is master to decide what law he will rely upon," *Fair* v. *Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913) (Holmes, J.), and may therefore sue only under state law whether or not the same allegations would support a federal-law cause of action. See, *e.g.*, *Merrell Dow*, 478 U.S. at 809 & n.6.

b. This Court's decisions in *Lohr* and *Riegel* strongly support the conclusion that Section 337 does not prohibit private suits to enforce state laws that parallel the requirements of the FDCA. In *Lohr*, after concluding that Section 360k does not preempt tort actions under state law if they "rest on claims that [the defendant] negligently failed to comply with duties 'equal to, or substantially identical to, requirements imposed' under [the FDCA]," the Court held that "there was no reason for

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[2] As explained above, California law imposes an independent state-law duty that requires the labeling of food that contains artificial coloring to state that fact. See Cal. Health & Safety Code § 110740 (West 2006). Moreover, respondents' claims, like the state-law tort claims in *Lohr*, require proof not only of violation of that state requirement but also of additional elements, such as damage or injury as a result of the violation. See Cal. Civ. Code § 1780 (West Supp. 2008) (requiring proof that damage resulted from the unfair or deceptive practice); Cal. Bus. & Prof. Code §§ 17204, 17535 (West 2008) (requiring proof of injury in fact and loss of money or property as a result of unfair competition or false advertising); *Apollo Capital Fund, LLC* v. *Roth Capital Partners, LLC*, 70 Cal. Rptr. 3d 199, 213 (Cal. App. 2007) (stating that proof of justifiable reliance and resulting damage is necessary to establish negligent misrepresentation). The existence of those additional elements reinforces the conclusion that respondents are not seeking to enforce the FDCA itself but rather to enforce a parallel state-law duty that the FDCA does not preempt. See also *Lohr*, 518 U.S. at 495 (explaining that the fact that plaintiffs must prove additional elements to prevail on their state-law claims does not make the state-law requirements "different from" federal requirements for preemption purposes).

the Court of Appeals to preclude" such claims. 518 U.S. at 497. The dissenting Justices agreed with that aspect of the Court's holding. See *id.* at 513 (opinion of O'Connor, J.). No Member of the Court suggested that parallel state-law claims might be precluded by Section 337. And if Section 337 imposed a blanket prohibition on such claims, the Court's holding that the claims in *Lohr* could proceed could not be sustained. Similarly, in *Riegel*, the Court concluded that state requirements for medical devices are preempted "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law," implicitly recognizing that the FDCA does not contain any generally applicable provision preempting such suits. 128 S. Ct. at 1011 (quoting 21 U.S.C. 360k(a)).

c. Petitioners nonetheless contend that Section 337 broadly preempts all private actions to enforce state laws that parallel FDCA requirements because, according to petitioners, courts had uniformly construed Section 337 to preempt such suits before Congress enacted the NLEA, and nothing in the NLEA changed the state of the law. Pet. 13-14, 17-21. Petitioners are wrong on both counts.

First, no uniform line of authority had interpreted Section 337 to preclude state-law causes of action before enactment of the NLEA. Petitioners cite only one court of appeals decision and two district court cases in support of their contention. The court of appeals decision did not address state-law claims. It held only that the FDCA does not itself provide a private right of action. *Pacific Trading Co.* v. *Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976). The two district court decisions held that state-law actions were preempted, but the decisions did not cite Section 337 in support of their preemption

holdings. See *Animal Legal Def. Fund Boston, Inc.* v. *Provimi Veal Corp.*, 626 F. Supp. 278, 283-284 (D. Mass.), aff'd, 802 F.2d 440 (1st Cir. 1986) (*Animal Legal Defense Fund*); *National Women's Health Network, Inc.* v. *A.H. Robins Co.*, 545 F. Supp. 1177, 1180-1181 (D. Mass. 1982) (*National Women's Health*). The courts relied primarily on what they described as the "comprehensive" or "pervasive" nature of the particular regulatory schemes—the regulations concerning medicated animal feeds and new animal drugs in *Animal Legal Defense Fund*, see 626 F. Supp. at 283-284, and the regulations concerning medical devices in *National Women's Health*, see 545 F. Supp. at 1181. In any event, as explained above, this Court has since concluded in both *Lohr* and *Riegel* that private suits can be brought based on violations of state law that parallel federal requirements.

Second, Section 343-1, which was enacted as part of the NLEA, signaled Congress's intent to permit States to adopt food-labeling requirements identical to FDCA requirements and to provide for the enforcement of those state requirements in state court. See pp. 8-11, *supra*. Indeed, petitioners concede that Section 343-1 authorizes States to sue to enforce such state requirements and that Section 337 does not preempt or otherwise limit those suits. Pet. 20. As the California Supreme Court recognized, that concession is fatal to petitioners' contention that Section 337 nonetheless preempts States from authorizing private suits to enforce the same state requirements. See Pet. App. 33-34. If Section 337(b)'s restrictions on a State's direct enforcement of the FDCA itself do not preempt or otherwise restrict a State's enforcement of its own parallel state requirements, then it follows that Section 337(a)'s re-

strictions on private enforcement of the FDCA likewise do not preempt a State from allowing private suits based on those parallel state requirements.

d. Petitioners contend that private actions to enforce parallel state requirements would frustrate the FDCA's goal of uniformity in regulation and enforcement. Pet. 21-27; Pet. Reply Br. 5. The interest in uniformity of regulation and enforcement under the FDCA is, however, not so "unyielding" as to bar all private state-law suits concerning food labeling. *Sprietsma* v. *Mercury Marine*, 537 U.S. 51, 70 (2002). As described above, Section 343-1 expressly allows States to impose food-labeling requirements that are identical to federal law. Section 343-1 also allows States to impose food-labeling requirements that are not identical to FDCA requirements in specified circumstances or when FDA grants an exemption from preemption. 21 U.S.C. 343-1(a)(1)-(5) and (b). And Section 337(b) even expressly allows States to bring actions to enforce the *federal* FDCA food-labeling requirements themselves. 21 U.S.C. 337(b). Thus, the interest in uniformity does not deprive the States of any role in enforcing food-labeling requirements.

In the view of FDA, private suits under state law to enforce state food-labeling requirements that parallel FDCA requirements do not necessarily pose a conflict with the FDCA or its enforcement scheme. On the contrary, the requirements of 21 U.S.C. 343-1 will ensure that any state-law action is consistent with federal requirements. Unless the state requirement is "identical" to the federal requirement, or the statute or FDA grants an exemption, the state-law suit will be preempted.

Even a suit to enforce an identical state requirement would be preempted if the particular suit "actually

conflict[ed]" with provisions of the FDCA, implementing regulations, or an administrative determination or enforcement action by FDA. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874 (2000). For example, FDA might resolve an enforcement action against a food company that had violated the FDCA's labeling requirements by entering into a consent decree under which the company agreed to change its labeling in a particular manner prospectively. FDA might decide, however, that the decree should affirmatively allow products already distributed to remain on the market because they did not present a health or safety risk, they provided recognized nutritional benefit, and the risk from their misbranding was negligible. Once the consent decree was approved by the court, a state-law action against the company to remedy the violation of an identical state labeling requirement might well be preempted, if it would actually conflict with the federal enforcement balance reflected in the consent decree.

Respondents' suit, however, does not pose any such conflict, and the California Supreme Court correctly held that it is not preempted. See *Lohr*, 518 U.S. at 496 ("Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,' *Hines*[, 312 U.S. at 67,] and, therefore, whether it should be preempted.") (footnote omitted).

B. The Decision Below Does Not Conflict With Any Decision Of This Court Or A Federal Court Of Appeals

1. Contrary to petitioners' contention (Pet. 12-13, 14-15; Pet. Reply Br. 11-12), the California Supreme Court's decision does not conflict with this Court's decision in *Buckman*. In *Buckman*, the Court held that the FDCA preempted state-law claims alleging that the defendant had made fraudulent representations to FDA in order to secure clearance to market certain medical devices. 531 U.S. at 343-344. The Court concluded that those claims conflicted with federal law because they would "skew[]" the "delicate balance of statutory objectives" that FDA was charged with achieving in policing fraud and administering the device clearance process. *Id.* at 348. The Court explained that, among other things, the claims might deter would-be applicants from seeking approval for beneficial devices or lead applicants to deluge FDA with information that the agency neither wanted nor needed to determine whether to approve the devices. *Id.* at 350-351. Unlike the suit in *Buckman*, respondents' suit does not involve alleged fraud on the FDA, the FDA's approval of a product, or any other FDA determination. Respondents' suit therefore does not pose the concerns about skewing the FDA's approval process on which this Court relied in *Buckman*.

As petitioners note (Pet. 14), in a footnote in *Buckman*, the Court stated in passing that the FDCA does not authorize private litigants to sue for noncompliance with the FDCA's medical device provisions. See 531 U.S. at 349 n.4 (citing 21 U.S.C. 337(a)). But, as explained above, respondents' suit is based on a violation of state law, not the FDCA itself.

2. The decision below also does not conflict with the decision of any federal court of appeals. Petitioners cite three court of appeals decisions and imply that those decisions conflict with the California Supreme Court's decision here. See Pet. 14-15 n.2. All three of those decisions stated that the *FDCA* does not create a *federal* private right of action. See *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781 (3d Cir. 1999); *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105 (2d Cir. 1997); and *Bailey* v. *Johnson*, 48 F.3d 965 (6th Cir. 1995). None of the decisions, however, addressed the distinct question at issue here—whether the FDCA preempts private actions under *state law* to enforce state requirements that are identical to federal requirements. The court of appeals decisions therefore do not conflict with the holding in this case.

C. The Decision Below Is Interlocutory

Even if the question presented otherwise warranted review, this Court should deny the petition for a writ of certiorari because the decision below is interlocutory. The California Supreme Court merely reversed the dismissal of respondents' complaint and remanded for further proceedings. The state courts therefore have not yet made any determinations concerning whether the elements of respondents' various state-law causes of action are satisfied, the nature of petitioners' conduct, or what form of relief, if any, might be available as a matter of state law. The proceedings on remand will yield more information about the precise contours of respondents' claims and may clarify the nature of any preemption issue that might be presented. Accordingly, it would be premature for the Court to grant review at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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* The Solicitor General is recused in this case.